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EXAMINER	
PANDE, SUCHIRA	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/517,698	TILLETT ET AL.	
	Examiner	Art Unit	
	Suchira Pande	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2006*.

2a)☐. This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *6,9,10,18,19,23-25,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-8,11-17,20-22,26-27 and 30-36* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of following species DNA sequencing as chemical reaction; DNA as reactant; mineral oil as inert phase; change in temperature as changes; and non-ionic surfactants as a surfactant for examination in the reply filed on November 24, 2006 is acknowledged.

Accordingly claims 6, 9-10, 18-19, 23-25 and 28-29 are withdrawn from further consideration as they are drawn to non-elected species. Claims 1-5, 7-8, 11-17, 20-22, 26-27 and 30-36 that read upon the elected species are being examined in this action.

Specification

2. The disclosure is objected to because of the following informalities: Brief Description of Drawings on pages 18, and 20-21 refer to Figures 1, 3, 4, 8, 9 and 11. While the Figures are labeled as 1.1, 3.1, 4.1, 8.1, 9.1, and 11.1 on pages 1, 3, 4, 19, 20 and 22 respectively in the specification. This discordance between the Figure numbers and the corresponding Brief Description of Drawings needs to be resolved.

Appropriate correction is required.

3. The use of the trademarks such as TRITON X-100™ and many others has been noted throughout this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Applicant is advised to scan the entire application for places where Trademarks have been used and make appropriate corrections.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22 contains many trademarks/trade names such as HECAMEG ™, THESIT ™ etc. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe non-ionic surfactants and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 7-8, 11-14, 16-17, 20-22 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneegaβ & Kohler (2001) Reviews in Molecular Biotechnology 82:101-121 as evidenced by Katsura et al. (2001) Electrophoresis 22: 289-293.

Regarding claims 1 and 4 Schneegaβ & Kohler teach: A method of performing a chemical reaction (See abstract and page 103 par. 2 where PCR is taught as a chemical reaction) between reactants comprising:

(a) subjecting an emulsion (see page 109 section 4.5 where two-phase system is taught) comprising

(i) a discontinuous first phase in which at least one of the reactants is present (see page 109 par. 3 where aqueous sample droplet is taught); and

(ii) a substantially continuous second phase (see page 109 par. 3 where continuous carrier flow of mineral oil is taught),

to a physical or chemical change such that a substantially continuous phase is formed from the discontinuous phase (Optical force of focused laser beam is taught as physical change by Katsura et al. See page 109 section 4.5 par. 2 where Schneegaβ & Kohler teach the two-phase system of Katsura et al. Katsura et al. evidence that the

chemical reaction (see Katsura et al. page 290 par. 1 where PCR amplification is taught) between different molecules is controlled by fusing two micro reactors. Optical force of focused laser beam is physical change used here to move the micro reactors to move towards each other and fuse see Katsura et al. page 291 Fig. 3 where fusion of micro reactor is taught to form a substantially continuous phase from the discontinuous phase); and

(b) providing conditions in which the chemical reaction between the reactants takes place (see page 110 section 4.7 par. 1 where successful PCR amplification using two phase water/oil micro reactor system of Katsura et al. is taught) .

Regarding claim 4 Schneegaβ & Kohler teach: a method of performing a chemical reaction between reactants in an aqueous phase (see page 109 par. 3 where aqueous sample droplet is taught for PCR).

Thus all elements of claims 1 and 4 are taught by Schneegaβ & Kohler as evidenced by Katsura et al.

Regarding claim 2, Schneegaβ & Kohler teach discontinuous first phase is an aqueous phase (see page 109 par. 3)

Regarding claim 3, Schneegaβ & Kohler teach continuous second phase is an inert or an organic phase (see page 109 par. 3).

Regarding claims 5 & 7, Schneegaβ & Kohler teach chemical reaction is DNA sequencing (see page 102 par. 5 where application of PCR for sequencing of human genome is taught)

Regarding claim 8, Schneegaβ & Kohler teach reactant is DNA (See above where PCR is taught as the chemical reaction by Schneegaβ & Kohler. Therefore they inherently teach that DNA is a reactant).

Regarding claim 11, Schneegaβ & Kohler teach wherein the aqueous phase is in a submicrolitre or microlitre volume (see page 118, par. 9 where amplification using microliter volume is taught).

Regarding claim 12, Katsura et al. teach wherein the emulsion comprises a single inert phase and two or more different aqueous phases (see Katsura et al. page 293 par. 1 where two different micro reactors containing different reactants in aqueous phase are taught. By teaching different reactants in different micro reactors Katsura et al. teach two different aqueous phases the single inert phase here is composed of rapeseed oil (see Katsura et al. section 3.1 on page 290).

Regarding claim 13, Katsura et al. teach wherein emulsion is prepared by combining a first and second emulsion wherein

(a) the first emulsion comprises a first aqueous phase and a first inert phase wherein the first aqueous phase comprises a first reactant (see Katsura et al. page 293 par. 1 where micro reactor is taught. One micro reactor is composed of first emulsion where a first aqueous phase contains yeast chromosomal DNA as reactant and oil as first inert phase—see above for claim 12); and

(b) the second emulsion comprises a second aqueous phase and a second inert phase wherein the second aqueous phase comprises a second reactant (see Katsura et al. page 293 par. 1 where micro reactor is taught. Second micro reactor is composed of

second emulsion where a second aqueous phase contains YOYO as reactant and oil as second inert phase—see above for claim 12).

Thus Katsura et al. teaches two water in oil emulsion microreactors that are fused to form one continuous aqueous phase in which the chemical reaction takes place.

Regarding claim 14, Katsura et al. teach wherein the first and second inert phases are the same (rapeseed oil see above as described for claims 12 and 13) but the first and second aqueous phases are different (see above as described for claims 12 and 13).

Regarding claims 16-17, and 20, Schneegaβ & Kohler teach wherein the inert phase is a non-polar water-immiscible compound or composition (see page 109 par. 3 where mineral oil is taught for generation of two phase system).

Regarding claims 21 -22, Schneegaβ & Kohler teach wherein the emulsion comprises a surfactant, TWEEN 20 (see page 110 par. 2 where a non-ionic surfactant TWEEN 20 is taught).

Regarding claim 34, Schneegaβ & Kohler teach a method of performing a chemical reaction between at least two reactants in an aqueous solution comprising:

(a) combining a first emulsion in which an aqueous solution comprising a first reactant is emulsified in a first inert phase, with a second emulsion in which an aqueous solution comprising a second reactant is emulsified in a second inert phase;

(b) subjecting the mixture to a physical or chemical change such that the emulsions collapse and the emulsified aqueous solution coalesces into a substantially single or substantially continuous aqueous phase;

(c) subjecting the aqueous phase to conditions in which the chemical reaction between the reactants take place. (see description above as applied to independent claims 1 and 4 and the dependent claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 15, 26-27 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneegaβ & Kohler (2001) Reviews in Molecular Biotechnology

82:101-121 as evidenced by Katsura et al. (2001) Electrophoresis 22: 289-293 as applied to claims 1-5, 7-8, 11-14 above, and further in view of Oberholzer et al. (1995) Chemistry and Biology vol. 2: 677-682 and Luisi et al. (1988) Biochimica et Biophysica Acta 947: 209-246 as evidenced by Gu and Galera-Gomez (1998) Colloids and Surfaces A: Physicochemical and Engineering Aspects 147: 365-370 .

Regarding claim 15, Schneegaβ & Kohler as evidenced by Katsura et al. teach method of claim 13 wherein the first an second inert phases are the same. But they do not teach wherein the first insert phase and the second inert phase are different.

Regarding claim 15, Oberholzer et al. teach wherein the first insert phase and the second inert phase are different (see page 679 par. 2 where two types of lipososmes obtained from POPC or from a 9:1 (w/w) mixture of POPC and PS are taught as two different inert phases to entrap PCR reagents.

Regarding claim 26-27, Schneegaβ & Kohler as evidenced by Katsura et al. teach method of claims 1 and 4 but do not teach use of change in temperature as the physical change.

Regarding claim 26-27, Luisi et al. teach change in temperature as the physical change to alter the phase behavior of oil water emulsions (see page 214 par. 3 and Fig. 3 also see page 215 and Fig. 4). Gu and Galera-Gomez clearly evidence how temperature causes the phase behavior of emulsions containing non-ionic surfactants such as TRITON X-100™ to change. See whole article.

Regarding claim 35, Schneegaβ & Kohler as evidenced by Katsura et al. teach. teach a method of performing a chemical reaction between at least two reactants in an

aqueous solution but do not teach performing a chemical reaction between at least two reactants in an organic solution.

Regarding claim 35 Oberholzer et al. teach a method of performing a chemical reaction in liposomes made of POPC and mixture of POPC/PC. Luisi et al. teach "Amphiphillic molecules, when dissolved in organic solvents are capable of self organization to form spheroidal aggregates. These are referred to as reverse micelles. Structurally they are reverse of normal micelles in that they have an external shell made up of the hydrocarbon chains of the amphiphilic molecules and the polar or charged head-groups, with the counter ions being localized in the interior of the aggregate. Water and several other polar solvents, e.g., glycerol and formamide, are readily solubilized in this polar core, forming in the case of water, a so-called 'water pool' "(see Luisi et al. page 209 par.1). Luisi et al. also teach that PC or Phosphatidylcholine is capable of forming reverse micelles (see page 221 par2-page 222 par.1-2 where properties of reverse micelles formed by dissolving PC in different solvents are taught).

Thus an emulsion made of PC in organic solvent will form reverse micelle which results in formation of a discontinuous organic phase.

Thereby depending on the nature of the chemical reaction that one of ordinary skill in the art wants to conduct, PC can be dissolved in appropriate solvent to form reverse micelle in which the reactant is entrapped. Section IX on page 235 of Luisi et al. teaches Enzymology in reverse micelles and goes on to say " to date only a few proteins have been reported which are not compatible with reverse micelle systems. This generality is an important feature in view of possible biotechnological applications--

------. The study of enzymatic mechanisms for enzymes located in reverse micelles can be performed by utilizing the same techniques as for aqueous solutions". Thus providing one of ordinary skill in the art a reasonable expectation of success in performing a chemical reaction in organic phase.

Thereby by teaching use of POPC/PC liposomes, Oberholzer et al. teach method of performing a chemical reaction between reactants in an organic phase.

It would have been prima facie obvious to one of ordinary skill in the art to practice the method of Oberholzer et al. in the method of Schneegaβ & Kohler as evidenced by Katsura et al. at the time the invention was made. The motivation to do so is provided to one of ordinary skill in the art by teachings of both Oberholzer et al. and Katsura et al.

Oberholzer et al. demonstrate that liposomes made of POPC are thermally stable under conditions to which PCR reactions are subjected (see Figs. 1-2) and point out that "In principle, one might carry out the reaction by first entrapping all of the macromolecular components—enzyme and DNA components in this case--- and then adding the deoxyribonucleotides in excess to permeate into the liposome from external aqueous milieu. We were unable, however, to find conditions under which such a permeation was possible with POPC liposomes, and we had to resort to the alternative method of entrapping all the reagents in the liposomes" (see Oberholzer et al. page 679 par. 1). They go on to say that "Liposomes composed of POPC or a mixture of POPC and PS are very stable at high temperatures, but only a small fraction of the liposomes could be filled with all of the reagents necessary for PCR". See Oberholzer et al. page

680 section Significance). So the limitation of their method is the fact that number of reagents required for PCR (namely template DNA, the two primers, 4 dNTPs, DNA polymerase and buffer) is more than 8 that need to be filled in each liposome as taught by Oberholzer et al.

Katsura et al. teach a method where individual components of a reaction mix can be enclosed in separate microreactors. By applying force these microreactors can be fused together such that the reactants present in the aqueous phase all come together and the chemical reaction occurs. This teaching of Katsura et al. provides the solution to the limitation faced by Oberholzer et al.

In light of the above teachings, one of ordinary skill in the art would be motivated to enclose individual reactants/components of the PCR reaction mix in separate emulsions. Then combine the emulsions, such that the mixture contains microreactors containing all the required components in aqueous phases enclosed in inert phase for the desired chemical reaction to proceed. Using appropriate technique the microreactors are fused such that all the reactants are now present in a continuous aqueous phase thus allowing the reaction to proceed under appropriate reaction conditions.

11. Claims 30- 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneegaβ & Kohler (2001) Reviews in Molecular Biotechnology 82:101-121 as evidenced by Katsura et al. (2001) Electrophoresis 22: 289-293 as applied to claims 1-5, 7-8, 11-14, 16-17 and 20-22 above, and further in view of Tawfik and Griffiths (1998)

Nat. Biotechnol. 16:652-656 as evidenced by Miller et al. (2001) Colloids and Surfaces A: Physicochemical and Engineering Aspects 183-185: 681-688.

Regarding claim 30, Schneegaβ & Kohler as evidenced by Katsura et al. teach method of claims 1 and 4 but do not explicitly teach wherein the ratio of the aqueous to inert phase is in the range of 1:4 to 1:19.

Regarding claim 30, Tawfik and Griffiths teach wherein the ratio of the aqueous to inert phase is 1:19 (see page 655 Experimental protocol section labeled Emulsified reactions where emulsion is made by adding 50μl of in vitro reaction (aqueous phase) to 0.950ml = 950μl of ice cooled oil phase (inert phase) is taught. Ratio of 50:950 translates into a ratio of 1:19). Tawfik and Griffiths do not teach the whole range from range of 1:4 to 1:19. However since prior art teaches successful generation of emulsion for carrying out reaction in microreactors for different purposes. An ordinary practitioner would have recognized that the results optimizable variables of ratio of the aqueous to inert phase could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented by applicant that the selection of recited ratios was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. Applicants do not provide any detail guidance as to why a certain ratio of say 1:4 would

be preferable over 1:19 taught by prior art. In fact Miller et al. (2001) Colloids and Surfaces A: Physicochemical and Engineering Aspects 183-185: 681-688 do show emulsions can be made using the full range recited in this claim (see Fig. 2 of Miller et al. where whole range of 1:4 to 1:19 is taught for making water/oil emulsions).

Regarding claim 31, Schneegaβ & Kohler as evidenced by Katsura et al. teach method of claims 1 and 4 but do not teach wherein the inert phase is removed from the substantially continuous aqueous phase after the chemical reaction has taken place.

Regarding claim 31, Tawfik and Griffiths teach wherein the inert phase is removed from the substantially continuous aqueous phase after the chemical reaction has taken place (see page 655, par.6 section entitled Emulsified reactions-- where removal of inert oil phase from the substantially continuous aqueous phase after the chemical reaction has taken place is taught).

Regarding claim 32, Tawfik and Griffiths teach wherein the inert phase is removed from the substantially continuous aqueous phase by suction or evaporation (see Tawfik and Griffiths page 655, par.6 where removal of inert oil phase is taught. Inert oil is dissolved in ether and ether phase is removed. The aqueous phase is washed with ether to remove any residual traces of oil and the ether is evaporated by applying suction using speedvac).

Regarding claim 33, Tawfik and Griffiths teach wherein the aqueous phase and the inert phase are submitted to the reaction conditions together (see page 655, par.5 where In vitro transcription/translation in emulsion is taught).

It would have been prima facie obvious to one of ordinary skill in the art to practice the method of Tawfik and Griffiths in the method of Schneegaβ & Kohler as evidenced by Katsura et al. at the time the invention was made. The motivation to do so is provided by Tawfik and Griffiths who describe a system that uses man-made cell-like compartments. These aqueous compartments of water-in-oil emulsions were used to perform coupled transcription and translation in emulsified droplets that were stable (see Tawfik and Griffiths Fig. 1.) The use of droplets allowed one gene per aqueous compartment to be analyzed. So a droplet of diameter (by volume) 2.6 μm requires use of extremely small amounts of reactants to perform the desired reactions. In addition whole library of genes can be processed simultaneously in different droplets/compartments. Compartmentalization prevents the modification of genes in other compartments. Emulsion is broken by addition of chemical, all reactions are stopped and the aqueous compartments are combined and the genes linked to the products are selectively amplified and further characterized (see page 653 legend of Fig. 1). Thus teaching one of ordinary skill in the art a method that is extremely economical due to use of miniscule amounts of expensive reagents and efficient for processing and analyzing large no of sample such as those desired for diagnostic DNA sequencing from patient samples. Since the emulsions can be broken by simply addition of a chemical hence the method taught by Tawfik and Griffiths provides an additional advantage to one of ordinary skill in the art to practice the method of Schneegaβ & Kohler because now they do not need the expensive equipment to generate the laser beams to fuse the microreactors as taught by Katsura et al.

Conclusion

12. Claims 1-5, 7-8, 11-17, 20-22, 26-27, 30-36 under examination are rejected over prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JEFFREY FREDMAN
PRIMARY EXAMINER
1/2/07

Suchira Pande
Examiner
Art Unit 1637